

Package leaflet:
Information for the user



Sinupret[®] extract

Coated tablets

Active substance:

Dry extract containing a mixture of gentian root, primula flowers, sorrel herb, elder flowers and verbena herb

For use in adolescents from the age of 12 years and adults

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Sinupret extract carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 7-14 days.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Sinupret extract is and what it is used for

Sinupret extract is an herbal medicine for inflammations of the paranasal sinuses.

Sinupret extract is used for acute, uncomplicated inflammations of the paranasal sinuses.

2. Before you take Sinupret extract

DO NOT take Sinupret extract

- if you have an existing stomach or duodenal ulcer or
- if you are allergic (hypersensitive) to gentian root, verbena herb, sorrel herb, elder flowers, primula flowers or any of the other ingredients of the medicine (for other ingredients, see under section 6 FURTHER INFORMATION).

Take special care with Sinupret extract

If symptoms persist for more than 7-14 days, get worse or periodically return, or if you experience nosebleeds, severe pain, pus-like nasal discharge, visual disturbances, asymmetry of the middle face or eyes or facial numbness, a doctor should be consulted, because these symptoms or findings for all kinds of inflammations of the paranasal sinuses are generally regarded as severe warnings that require an examination by a medical specialist and urgent treatment.

In known cases of stomach inflammation and patients with a sensitive stomach, particular caution is required when taking this medicine. You should preferably take Sinupret extract after meals and with a glass of water.

Children

The medicine should not be used in children under 12 years of age.

To date, no adequate studies are available for the use of Sinupret extract in children under 12 years of age.

Taking other medicines

No systematic interaction studies have been conducted. For this reason, it cannot be ruled out that the effect of other medicines may be enhanced or weakened.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

For safety reasons, use of Sinupret extract during pregnancy should be avoided.

It is not known whether the active substances of Sinupret extract pass into breast milk. You should therefore not use Sinupret extract during breast-feeding.

Driving and using machines

No special precautions are required.

Important information about some of the ingredients of Sinupret extract

This medicine contains the sugars glucose and sucrose. If you know that you have an intolerance to certain sugars, please consult your doctor before taking Sinupret extract.

3. How to take Sinupret extract

Always take Sinupret extract exactly as instructed in this leaflet. You should check with your doctor or pharmacist if you are not sure.

Unless prescribed otherwise by the doctor the usual dose is:

Adults and adolescents from the age of 12 years take 1 coated tablet, 3 times daily.

This medicine is not intended for use in children under 12 years of age.

There are insufficient data for specific dosage recommendations in patients with impaired kidney/liver function.

Method of administration

Sinupret extract is swallowed with some liquid (e.g. a glass of water) without chewing 3 times a day (morning, noon and evening). Sinupret extract can be taken with food, drinks or even independently of meals. If you have a sensitive stomach, you should preferably take Sinupret extract after meals.

Duration of use

Unless otherwise prescribed, the duration of use is: 7-14 days. If no improvement occurs within this time, please consult a doctor.

If you take more Sinupret extract than you should

If you take more Sinupret extract than you should, please tell a doctor. He/she can decide on any measures that may be required. The side effects listed below (e.g. nausea, stomach ache, diarrhoea) may appear in a more intense form.

If you forget to take Sinupret extract

If you happen to take too little by mistake, or if you forget to take Sinupret extract, do not take a double dose at the next time. Continue to take Sinupret extract as prescribed by your doctor or as described in this leaflet.

If you stop taking Sinupret extract

As a rule, Sinupret extract can be discontinued without any harm. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Sinupret extract can cause side effects, although not everybody gets them.

Significant side effects or signs you should look out for, and what to do if you are affected

Common side effects (1 to 10 out of 100 patients treated)

Gastrointestinal complaints, e.g. nausea, flatulence, diarrhoea, dry mouth, stomach ache.

Uncommon side effects (1 to 10 out of 1,000 patients treated)

Hypersensitivity reactions of the skin (e.g. skin rash, redness, itching), dizziness.

Side effects with unknown frequency (frequency cannot be estimated on the basis of the data available)

Severe allergic reactions (swelling of the lips, tongue and throat and/or larynx with airway constriction, shortness of breath, facial swelling)

At the first signs of a hypersensitivity reaction, Sinupret extract must not be taken again.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Bundesinstitut für Arzneimittel und Medizinprodukte [Federal Institute for Drugs and Medical Devices], Abt. Pharmakovigilanz [dept. Pharmacovigilance], Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sinupret extract

Do not store above 30°C.

Keep out of the sight and reach of children.

Do not use Sinupret extract after the expiry date which is stated on the box and the blister. The expiry date refers to the last day of that month.

6. Further information

What Sinupret extract contains

Composition:

1 coated tablet contains:

Active substance:

160.00 mg dry extract (3-6:1) of gentian root, primula flowers, sorrel herb, elder flowers, verbena herb (1:3:3:3:3) 1. Extracting agent: ethanol 51%

The other ingredients are:

Spray-dried gum arabic, calcium carbonate, carnauba wax, cellulose powder, microcrystalline cellulose, chlorophyll powder 25% (E140), dextrin (from corn starch), glucose syrup, hypromellose, indigocarmine, aluminium salt (E 132), magnesium stearate (Ph.Eur.) [vegetable], maltodextrin, riboflavin (E 101), highly dispersed silicon dioxide, highly dispersed hydrophobic silicon dioxide, stearic acid, sucrose, talc, titanium dioxide (E 171).

Note for diabetics:

One coated tablet contains on average 0.026 carbohydrate exchange units (CEU). Sinupret extract is gluten-free and lactose-free.

What Sinupret extract looks like and contents of the pack

Packs with 20 (N 1) coated tablets, 2 blisters each containing 10 coated tablets. Packs with 40 coated tablets, 4 blisters each containing 10 coated tablets. Hospital pack with 400 (10 x 40) coated tablets.

Sinupret extract are green, round, biconvex coated tablets with a smooth surface.

Marketing Authorisation Holder and Manufacturer

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